UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM **Date: December 19, 2019**

SUBJECT: Registration Review Draft Risk Assessment for Fenpropimorph

PC Code: 121402	DP Barcode: 455137
Decision No.: 557228	Docket No: EPA-HQ-OPP-2014-0404
Regulatory Action: Registration Review	Case No.: 5112
Risk Assessment Type: DRA	CAS No.: 67564-91-4

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This document provides the draft human health and ecological risk assessment conducted in support of the antimicrobial pesticide active ingredient (AI) Fenpropimorph.

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1 EXECUTIVE SUMMARY

The active ingredient, fenpropimorph, is a systemic morpholine fungicide registered for use as an antisapstain on wood products. It is used to control sapstain, mold and decay on green or freshly cut lumber and products such as logs, poles, posts, composites, veneers and wood chips.

Human Health

There are no residential or dietary uses for fenpropimorph. Furthermore, the Agency is not establishing dermal points of departure for any exposure duration as the uses are only occupational and it is expected that workers will wear the personal protective equipment (PPE) required on the label to prevent irritation. Therefore, only occupational inhalation exposure was assessed. The occupational inhalation margins of exposure (MOEs) are not of concern, if the clean-up crew workers wear respiratory protection, as they are all above the level of concern (LOC) of 100.

Environmental Fate and Effects

Environmental exposures are expected to be low because the label restricts storage of treated lumber and additionally, this product is intended to protect wood prior to sale and is not intended to protect lumber at the use site. Fenpropimorph also has low leach rates as well as limited soil mobility and is not expected to reach aquatic environments.

Therefore, risks to aquatic and terrestrial organisms are not expected due to the limited exposure potential.

EPA is making a "no effect" determination under the Endangered Species Act (ESA) for all listed species and designated critical habitats, and has, therefore, concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under ESA section 7(a)(2) is not required for the antisapstain use of fenpropimorph on wood products.

2 INTRODUCTION

2.1 Case Overview

Fenpropimorph was first registered with the Agency in 1998 with the sole use as an antisapstain for wood treatment. A fenpropimorph Reregistration Eligibility Decision (RED) was not completed because the first pesticide product formulated with fenpropimorph was registered after November 1, 1984. A Registration Review docket for fenpropimorph has been established at http://www.regulations.gov in docket number EPA-HQ-OPP-2014-0404. A registration review GDCI-121402-1481 was issued June 9, 2017.

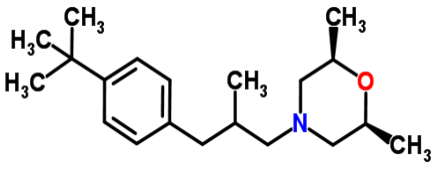
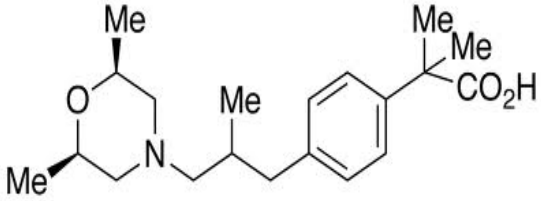
2.2 Recent Regulatory Actions

There are no recent regulatory activities for this chemical since the 2009 risk assessment (U.S. EPA, 2009).

2.3 Ingredient Profile and Chemical Identity

Table 1 presents the active ingredient to be assessed in case 5112 and Table 2 presents the chemical and physical properties of parent fenpropimorph (PC Code 121402) and its only degradate, fenpropimorph acid (PC Codes 621402, 621602). Product chemistry data for fenpropimorph acid were not submitted to the Agency, and as a result, the Agency accessed other sources of information.

Table 1 – Chemical Identification of Fenpropimorph

Chemical Name	Fenpropimorph	Fenpropimorph acid (degradate)[1]
Chemical Classification	Morpholine	Morpholine
PC Code	121402	621402, 621602
CAS Number	67564-91-4	121098-45-1
Molecular Formula	$C_{20}H_{33}NO$	$C_{20}H_{31}NO_3$
Molecular Weight (grams/mole)	303.48	333.47
Smiles code	CC1CN(CC(O1)C)CC(C)Cc2ccc(cc2)C(C)(C)C	CC1CN(CC(O1)C)CC(C)Cc2ccc(cc2)C(C)(C)C(=O)(O)
Molecular Structure		

[1] Based on EPI-WEB 4.11

Table 2 – Physical-Chemical and Environmental Fate Properties for Fenpropimorph and Fenpropimorph Acid

Guideline No.	**Parameter**	**Fenpropimorph**	**Fenpropimorph Acid (degradate)[7]**
Physical/Chemical Properties			
830.7050	UV/Visible Absorption	No measurable UV absorption at ≥290 nm at 25°C.[1]	Expected to be similar to parent fenpropimorph, no UV-Visible sorption at ≥290 nm

Guideline No.	Parameter	Fenpropimorph	Fenpropimorph Acid (degradate)[7]
830.7370	Dissociation constant	pK_a: 6.98 (20°C); pK_b 7.02 @ 20°C and 7.19 at 25°C[2]	Not available
830.7550	Octanol-water partition coefficient at 25 °C (Log K_{ow})	2.6 (22°C, pH 5) 4.1 (22°C, pH 7) 4.4 (22°C, pH 9)[3]	0.7
830.7840	Solubility in water (mg/L)	pH 7: 4.32 mg/L at 20°C; pH 9-11: 3.53 mg/L at 20°C [4]	16.7
830.7950	Vapor pressure (mm Hg)	2.63×10^{-5} at 20°C; 4.88×10^{-5} at 25°C[5]	Similar to parent compound, questionable estimate in EPI-WEB 4.11[8]
None (calculated)	Henry's Law (atm m^3 mol^{-1}) (assumes pH 7 and 25 °C)[6]	4.5×10^{-6}	1.28×10^{-6}

[1] MRID 46074201
[2] MRID 45857202
[3] MRID 45857203
[4] MRID 45857201
[5] MRID 46097502
[6] atm-m^3/mol = atmosphere cubic meter per mole; °C = degrees Celsius; mg/L = milligrams per liter; mmHg = millimeters of mercury; Henry's Law constant=[VP (mm Hg) x MW (g/mol)]/[760 * SOL (mg/L)]
[7] EPI-WEB 4.11, http://www.epa.gov/oppt/exposure/pubs/episuitedl.htm
[8] VP of 4.88 x 10-5 mm Hg for parent compound used for Henry's Law calculations

2.4 Use Pattern

There are currently two antimicrobial products that contain fenpropimorph, one manufacturing use product (MUP) and one end use product (EUP). The MUP (Fenpropimorph MUP, Reg. No. 7969-203) contains 96% active ingredient (w/w) and is used to formulate the EUP. The EUP, (Sinesto PFB, Reg. No. 71406-4), is used as a materials preservative and contains 5.4% fenpropimorph, 2.7 % propiconazole (PC Code 122101, Case # 3125, EPA-HQ-OPP-2015-0459), and 9 % boric acid (PC Code 011001, Case # 0024, EPA-HQ-OPP-2009-0306). The boric acid/sodium salts Proposed Interim Registration Review Decision (U.S. EPA, September 30, 2016) contains the risk assessment for boric acid. A risk assessment for propiconazole will be conducted during its registration review. This DRA contains the risk assessment for fenpropimorph and fenpropimorph acid only.

The EUP, Sinesto PFB, is used to control sapstain, mold and decay on green or freshly cut lumber and wood products (*e.g.,* logs, poles, posts, composites, veneers, wood chips/sawdust).

The sole active end-use label states that treated lumber "must be stored under cover, indoors, or at least 100 feet from any pond, lake, stream, wetland, or river to prevent possible runoff of the product into the waterway." The label also states that "the product is intended to provide sapstain, mold and decay control during storage and transit which is not intended to extend to the

end-use site." The product is intended to be efficacious under storage and transport conditions and not end-use conditions for lumber.

3 HUMAN HEALTH RISK ASSESSMENT

3.1 Data Deficiencies

The Agency is lacking an inhalation toxicity study. In lieu of an inhalation toxicity study to assess the inhalation risk, the Agency is using a reproduction and fertility effects toxicity study.

The Agency received a waiver for the immunotoxicity study. The waiver was evaluated by HASPOC on December 17, 2019, and it was granted.

3.2 Tolerance Considerations

The Agency has established a tolerance for fenpropimorph when used on imported bananas.

3.3 Label Recommendations

The Agency recommends labels of end-use products that contain fenpropimorph as an active ingredient state that clean-up crews wear a PF-10 respirator (*e.g.,* filtering face-piece respirator). This recommendation is being made to mitigate the inhalation risks and waive the need for an inhalation route-specific inhalation toxicity study (US EPA, TXR#0057984).

3.4 Anticipated Exposure Pathways

Occupational exposure to products that contain fenpropimorph when used as a wood preservative will occur via the dermal and inhalation routes (there are no residential exposures to fenpropimorph).

3.5 Hazard Characterization and Dose-Response Assessment

3.5.1 Summary of Toxicological Effects

A review of the toxicological database on fenpropimorph demonstrates that fenpropimorph can induce effects in the liver. However, these effects, which include hypertrophy and increases in liver enzyme levels are not considered adverse but are considered adaptive. The hypertrophy observed in the dosed animals is also observed at similar levels in controls and do not follow a toxicological dose response. The increase in liver enzyme levels does not reach a value (~300% increase) the Agency considers an adverse effect. Single cell necrosis is observed in a 90-day oral rat study and it is confounding as the control animals also demonstrate the effect and the study authors only analyzed the animals exposed at the high dose (1.54 mg/kg/day in males and 1.80 mg/kg/day in females) during a 6-week recovery period, eliminating the possibility to compare dosed and control animals during that specific study period. An analysis of liver single cell necrosis from the control animals and the animals exposed to the low dose and the mid-dose

during the recovery period, make it impossible to determine if the effect observed was due to exposure to fenpropimorph.

No effects were observed in rats exposed to fenpropimorph in a route-specific dermal study (MRID 45868902). The doses at which the rats were exposed in the dermal study were chosen based on a dose range finding study performed by the registrant in rats that showed dermal irritation (multifocal scale formation) at 0.1% w/w (4 mg/kg/day). Therefore, the animals were exposed to doses at which irritation was not expected to occur.

The Agency is lacking an inhalation toxicity study. Therefore, the Agency used a reproduction and fertility effects study (MRID 44323915) in rats to quantify the potential risk from exposure to fenpropimorph via the inhalation route. The Agency reviewed the reproduction and fertility effects study in rats as well as prenatal developmental toxicity studies in rats and rabbits. In the reproduction and fertility effects study, no adverse effects in the parents or offspring were observed and no reproductive effects were observed at any dose level tested. In the prenatal developmental toxicity studies, a common adverse effect observed in the offspring throughout the database was cleft palate. However, this effect was observed at the same doses at which maternal effects were observed and the NOAEL selected for inhalation exposure scenarios is protective of this effect, demonstrating that there is no susceptibility from exposure to fenpropimorph to the developing embryo or offspring. In a prenatal rat developmental study (MRID 44380108) body weights and body weight gains were decreased and vaginal bleeding was observed. At the same dose (160 mg/kg/day), the amount of live fetuses/dam was decreased and increases in resorptions and post implantation losses were observed. These same effects were observed in another developmental study in rats (MRID 44323912), however, at a lower dose (40 mg/kg/day). In the rabbit prenatal developmental studies (MRIDs 44323913 and 44323914), increased incidences of skeletal anomalies and variations were also observed.

A review of the database demonstrated that rats are the most sensitive species to the toxic effects of fenpropimorph compared to mice, rabbits and dogs. The doses at which developmental effects to the offspring were observed, were at the same doses at which maternal effects were observed. Therefore, there is no susceptibility to the developing fetus or to the offspring.

A review of the genetic toxicology database for fenpropimorph demonstrates that the chemical does not induce genetic damages in the Ames assay, chromosomal aberration assay using Chinese hamster lung cells, the micronucleus assay, or unscheduled DNA synthesis assay in primary rat hepatocytes. In addition, the Agency has classified fenpropimorph as “not likely to be carcinogenic to humans” (USEPA, 2005).

Fenpropimorph has been classified as Toxicity Category III for acute oral and dermal and IV for acute inhalation exposures. Fenpropimorph is severely irritating to the eye and the skin

(Toxicity Category I) and it has not been classified as to its dermal sensitization potential. Table 3 contains the summary of toxicological doses and endpoints for fenpropimorph. A search in Incident Data System on November 26, 2019 did not identify any human incidents associated with the use of fenpropimorph.

3.5.2 Safety Factor for Infants and Children (FQPA Safety Factor)

There is the potential to be exposed to fenpropimorph via imported bananas as there is an import tolerance established for such uses. The FQPA factor has been reduced to 1X based on the last assessment performed by the Health Effects Division (USEPA, 2006). The FQPA factor was reduced to 1X because: (1) the low degree of concern for the qualitative susceptibility in developmental and rabbit studies as fetal effects were observed only in the presence of maternal toxicity; (2) no concern for pre or post-natal toxicity since no offspring toxicity was seen in the two-generation study; (3) the endpoints of concern are addressed in this risk assessment; and (4) the dietary exposure assessment performed at that time assumed tolerance level residues and 100% crop treated.

3.5.3 Toxicity Endpoint and Point of Departure Selections

Uses of antimicrobial pesticide products composed of fenpropimorph as an active ingredient lead to dermal and inhalation (short-, intermediate-, and long-term durations) exposures. The Agency is establishing points of departure and endpoints for dermal and inhalation exposures of all durations, but not for dietary or incidental oral exposures.

3.5.3.1 Acute Dietary (all populations), Chronic Dietary (all populations) and Incidental Oral (any duration)

Points of departure for these scenarios are not being established as previous chronic dietary assessments for fenpropimorph (USEPA, 2006) demonstrated that the highest %aPAD was 2.6% using an acute point of departure of 15 mg/kg/day (cPAD = 0.15 mg/kg/day) and the highest %cPAD estimated was 11% using a point of departure of 3.2 mg/kg/day (cPAD = 0.032 mg/kg/day). Using a point of departure based on the two-generation toxicity study in rats of 2.04 mg/kg/day, would not increase the %cPAD significantly nor would it lead to an increased risk from inducing adverse health effects from direct consumption of imported bananas treated with fenpropimorph.

3.5.3.2 Dermal short- (1-30 days), intermediate- (1-6 months), long-term (>6 months)

The Agency is not establishing dermal points of departure for any exposure duration as the uses are limited to occupational scenarios and the label requires the necessary personal protective equipment (PPE) to mitigate potential dermal irritation.

3.5.3.3 Inhalation short- (1-30 days), intermediate- (1-6 months), long-term (>6 months)

The reproduction and fertility effects study in rats (MRID 44323915) was selected to evaluate inhalation short-, intermediate-, and long-term exposures. A LOAEL was not established as no effects were observed at the highest dose tested (2.04 mg/kg/day). Therefore, the NOAEL established is 2.04 mg/kg/day. This study is appropriate for the durations of exposure and establishment of the point of departure as it is protective from potential health effects that could be incurred from inhalation exposures during the occupational use of this chemical.

The uncertainty factors established for short, intermediate, and long-term inhalation exposures are 10x for interspecies extrapolation from animal to human and 10x for potential variation in sensitivity among members of the human population (intraspecies) (UF = 100x). The 100x uncertainty factor is justified based on the route-to-route extrapolation assessment of inhalation exposure to the aerosols of fenpropimorph (low vapor pressure). The inhalation MOEs are greater than 1,000 except for one scenario (*i.e.,* clean-up crews for the sapstain control use). For the clean-up crew workers, respiratory protection (*i.e*., filtering face-piece respiratory with a PF10) is required to achieve an extra 10x database uncertainty factor to waive the route-specific inhalation toxicity study based on the route-to-route extrapolation assessment.

Table 3: Summary of Toxicological Doses and Endpoints for Fenpropimorph

Exposure/ Scenario	Point of Departure	Uncertainty Factors	Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute or Chronic Dietary	Acute or chronic dietary points of departures do not have to be established as a previous dietary assessment demonstrated no risks from acute dietary exposures to imported bananas.			
Incidental Oral (Any duration)	Incidental oral (any duration) points of departures do not have to be established as a previous dietary assessment demonstrated no risks from chronic dietary exposures to imported bananas.			
Dermal Short- (1-30 days), Intermediate Term (1-6 months), and Long Term (>6 months)	Dermal points of departure are not being selected for occupational uses as the labels state personal protective equipment must be worn to protect from the irritating effects of fenpropimorph.			
Inhalation Short-Term (1-30 days) Intermediate-Term (1-6 months Long-Term (>6 months)[A]	NOAEL= 2.04 mg/kg/day [M]	UF_A = 10x UF_H = 10x	LOC for MOE = 100[A]	MRID 44323915 Reproduction and Fertility Effects study in rats. Parental/Reproduction/Offspring LOAEL: Not established
Cancer (oral, dermal, inhalation)	No increased incidences in tumors in chronic/carcinogenicity studies performed in rats, dogs, and mice (MRIDs 44380106, 44323911, 44380107). Classification: Not likely to be carcinogenic to humans.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). MOE = margin of exposure. LOC = level of concern.

[A] In the absence of an inhalation route-specific study, a 10X database uncertainty (DB_{UF}) factor will be used to screen risk for inhalation scenarios until an inhalation toxicity study is submitted or other information is provided to support a waiver. Based on the inhalation exposure/ risk profile for the current registered uses of fenpropimorph assessed in this document, the addition of a PF10 respirator to the label directions for clean-up crews for the sapstain control use would mitigate inhalation exposure concerns for the MOEs that fall below the extra 10X DB_{UF}. With the use of respiratory protection for the clean-up crew workers, a route-specific inhalation toxicity study would not be needed, and the Agency could waive the need for the inhalation study, pending finalization of modified labels (US EPA, TXR#0057984).

3.6 Dietary Exposure Risk Assessment

3.6.1 FFDCA Clearances

The Agency previously established a tolerance for fenpropimorph when used in imported bananas.

3.6.2 Food Exposure Profile

There are no registered food uses for fenpropimorph in the US (there is an import tolerance for bananas).

3.6.3 Water Exposure Profile

The potential for drinking water exposure to fenpropimorph from ingestion of surface and ground water in the vicinity of fenpropimorph-treated wood is expected to be negligible. The leaching rate of parent fenpropimorph from a rainfall study (MRID 46074205) was low, which is consistent with the limited water solubility of 3.5-4.3 mg/L (Table 4). Environmental residues are expected to be low and dispersed due to the widespread geographical distribution of the treated wood and label restrictions regarding the storage of treated wood (stated in section 4).

The potential for drinking water exposure to fenpropimorph from ingestion of surface and ground water in the vicinity of industrial use sites is also not expected. The sole end-use label states that wastes must be treated as hazardous waste and disposal must be conducted according to label instructions, a state pesticide or environmental control Agency, or by guidance from a hazardous waste representative. Further, fenpropimorph is not mobile in soil (section 4.1) and any transport of fenpropimorph to ground or surface water is not expected.

Therefore, no drinking water exposure is expected.

3.6.4 Residential (Non-Occupational) Exposure/Risk Characterization

There are no residential uses and no expected residential exposure for fenpropimorph.

3.6.5 Aggregate Exposure/Risk Characterization

There is an import tolerance for bananas and no other registered food uses, no residential incidental oral exposures, and drinking water exposure is expected to be minimal. The aggregate assessment is limited to the dietary exposure to bananas. As discussed in Section 3.5.3.1 above, the previous chronic dietary assessments for fenpropimorph (USEPA, 2006) demonstrated that the highest %aPAD was 2.6% using an acute point of departure of 15 mg/kg/day and the highest %cPAD estimated was 11% using a point of departure of 3.2 mg/kg/day. Using a point of departure based on the two-generation toxicity study in rats of 2.04 mg/kg/day, would not increase the %cPAD significantly nor would it lead to an increased risk from inducing adverse health effects from direct consumption of imported bananas treated with fenpropimorph. Therefore, there is no acute or chronic aggregate risks of concern.

3.6.6 Cumulative Exposure/Risk Characterization

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to fenpropimorph and any other substances and fenpropimorph does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fenpropimorph has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

3.7 Occupational Exposure/Risk Characterization

3.7.1 Short (ST)-/Intermediate (IT)-/Long-Term (LT) Handler Risk

According to the label, the uses include applying the product via bulk dip tanks and conventional spray systems as well as via low volume spray systems to, "control sapstain, mold and decay on green or freshly cut lumber and wood products like *e.g.* logs, poles, posts, composites, veneers and wood chips/sawdust or other similar byproducts."

The occupational exposure scenarios assessed in this document for the uses of fenpropimorph are shown in Table 4. The table also shows the application rates associated with the uses.

Table 4: Exposure Scenarios Associated with Occupational Exposures to Fenpropimorph

Representative Use	Method of Application	Exposure Scenario	Application Rate
Wood Preservative (non-pressure treated)	Low Pressure Spray	ST, IT and LT Handler: dermal and inhalation	The label states10% concentration of product.

Representative Use	Method of Application	Exposure Scenario	Application Rate
			10% product in treatment solution x 5.4% fenpropimorph in product = **0.54% fenpropimorph in treatment solution**
	Bulk dip tank[A,B] Conventional spray[A,B]	ST, IT and LT Handler: dermal and inhalation	The label states 3.5% concentration of product. 3.5% product in treatment solution x 5.4% fenpropimorph in product = **0.189% fenpropimorph in treatment solution**

A. For the assessment of handlers dealing with bulk dip tanks and conventional spray, the proprietary sapstain task force study was utilized. "*Measurement and Assessment of Dermal and Inhalation Exposures to Didecyl Dimethyl Ammonium Chloride (DDAC) Used in the Protection of Cut Lumber (Phase III)"* (Bestari *et al*., 1999).

B. There is no product-specific density available, so for purposes of this assessment, the product is assumed to have the density of water.

3.7.2 Sapstain Control- Worker Inhalation Exposures

The MOEs for sapstain control worker inhalation exposures to fenpropimorph aerosols were assessed as outlined in Table 5. The MOEs are not of concern, if the clean-up crew workers wear respiratory protection, because they are higher than the target MOE of 100.

Table 5: Sapstain Control Worker Inhalation MOEs for Fenpropimorph

Application Rate[A]	**Job Function**	**Unit Exposure[B] (mg/m^3/% ai)**	**Exposure[C] (mg/m^3)**	**Inhalation Dose[D] (mg/kg/day)**	**Inhalation MOE[E]**
0.189% fenpropimorph in the Treatment Solution for Dip tank and conventional Spray	Dip Tank Operator Millwright Chemical Attendant Clean-up Crew	0.0052 0.0031 0.0043 0.111	0.00098 0.00059 0.00081 0.021	0.000123 0.0000732 0.000102 0.00262	16000 27000 20000 760[F]
0.54% fenpropimorph in the Treatment Solution for Low Pressure Sprayer	Millwright Chemical Attendant Clean-up Crew	0.0031 0.0043 0.111	0.0017 0.0023 0.060	0.0002093 0.0002903 0.0074925	9600 6900 270[F]

A. Based on label 71406-4 which contains 5.4% ai. With label directions to dilute to 3.5% product in solution for dip tank and conventional spray applications and 10% for low pressure sprayer

B. Unit exposures are from the Sapstain Phase III study (MRID 455243-01).

C. Exposure (mg/m$_3$) = Application Rate (% ai) * Unit Exposure (mg/m^3/% ai)

D. Inhalation Dose = [Inhalation Exposure (mg/m^3) * Breathing Rate (1.25 m^3/hour) * 8 hours] / BW (80 kg)

E. Inhalation MOE = NOAEL (2.04 mg/kg/day) / Exposure (mg/kg/day), Target MOE is 100.

F. In the absence of a route-specific inhalation toxicity study, a 10X database uncertainty factor is used to support the waiver for the inhalation toxicity study. Based on the inhalation exposure/ risk profile for fenpropimorph, the addition of a PF10 respirator to the label directions for clean-up crews after dipping and spraying is needed to mitigate inhalation exposure concerns. Therefore, the Agency could waive the need for the inhalation toxicity study (and the inhalation risk of concern) once the labels are modified to include respiratory protection for the clean-up crews (*e.g.,* filtering face-piece respirator affording a PF10).

3.7.3 Post-Application Risk

No post-application exposures are expected from sapstain treatment.

4 ENVIRONMENTAL RISK ASSESSMENT

An ecotoxicity risk assessment for fenpropimorph was completed in 2007 and identified a potential for level of concern (LOC) exceedance for chronic risk to aquatic organisms (U.S. EPA, 2007). It was determined that fenpropimorph converts to fenpropimorph acid in the environment and was detected in laboratory sediment studies at up to ~10% of initial fenpropimorph concentration. At that time, the Agency concluded that additional plant, marine organism, and sediment-organism toxicity studies were needed for assessment of fenpropimorph and fenpropimorph acid.

The Agency also stated in the 2007 assessment that the label would need to be amended to include: "[Treated lumber] must be stored under cover, indoors, or at least 100 feet from any pond, lake, stream, wetland, or river to prevent possible runoff of the product into the waterway. Treated lumber stored within 100 feet of a pond, lake, stream, wetland, or river must be either covered with plastic or surrounded by a berm to prevent surface water runoff into the nearby waterway. If a berm or curb is used around the site, it must consist of impermeable material (clay, asphalt, concrete) and be of sufficient height to prevent runoff during heavy rainfall events."

In 2009, the additional data required in the 2007 risk assessment were submitted to the Agency. Using these new data and additional treated wood storage restrictions, a revised risk assessment was completed (U.S. EPA, 2009).

4.1 Environmental Fate

4.1.1 Available Data

Based on a wood leaching study using rainfall (MRID 46074205), fenpropimorph used as an antisapstain product is released to the environment as parent fenpropimorph with an average leach rate of 0.18 µg/cm^2/day for an extended period of time due to the relatively-low water solubility of 3.5-4.3 mg/L (Table 4). Leached residues of parent fenpropimorph will largely partition to soil and sediment based on a leaching adsorption/desorption study (MRID 45857318). Based on its low vapor pressure and Henry's Law Constant, it is unlikely to move from soil or water into air (Table 4). Fenpropimorph is persistent in aerobic soil (MRID 45857217) but is not mobile (MRID 45857218)[1]. As a result, transport of parent fenpropimorph by runoff to surface water and by leaching to ground water from treated wood is not expected.

[1] Log Koc values of 0-2 are mobile to highly mobile and Log Koc values of 3-4 are considered to be slightly mobile (http://www.fao.org/docrep/003/x2570e/x2570e06.htm)

Fenpropimorph acid only formed at significant quantities under aerobic aquatic conditions (MRID 45868904). Fenpropimorph acid was mobile to highly mobile in two soils (MRID 45857218). However, the Agency expects environmental residues of parent fenpropimorph and fenpropimorph acid to be low because the label restricts storage of treated lumber, and the product is intended to protect wood prior to sale and is not intended to protect lumber at the use site. Fenpropimorph also has low leach rates as well as limited soil mobility and is not expected to reach aquatic environments.

Table 6 contains a summary of the environmental fate data for both parent fenpropimorph and the degradation product fenpropimorph acid.

Table 6: Environmental Fate Data for Fenpropimorph and Degradation Products

Guideline	Parameter ($T_{1/2}$ unless stated)	Significant degradation products	Reference (MRID)/ Comments
Hydrolysis (835.2120)	Stable in pH 3, 5, 7, and 9	None	45857216 25 ºC
Photodegradation in water (835.2240)	No data	None	45857219 Compound does not absorb UV/Visible light above 290 nm
Aerobic soil metabolism (835.4100)	$T_{1/2}$ of 301 days and DT_{90} of 1,000 days for loamy sand soil r^2=0.77, Chi^2=7.3 (<15 %)	No significant degradation products	45857217 25 ºC Non-linear regression, non-transformed data, Single first order (SFO)
	$T_{1/2}$ of 302 days and DT_{90} of 1,000 days for loamy sand soil r^2=0.66, Chi^2=7.9 (<15 %)	No significant degradation products	
Aerobic aquatic metabolism (835.4300)	DT_{50} of 59 days and DT_{90} of 197 days (loamy sand system) r^2=0.92, Chi^2=7 %(<15 %)	Fenpropimorph acid increased to 22.6 % by 100 days and did not degrade	45868904 25 ºC Non-linear regression, non-transformed data, Single first order (SFO) for both systems Formation-decline analysis used for second sediment: water system
	DT_{50} of 38 days and DT_{90} of 125 days (loamy sand system) r^2=0.84, Chi^2=13.1 % (<15 %)	Fenpropimorph acid DT_{50} of 28 days and DT_{90} of 94 days (freshwater system) r^2=0.84, Chi^2=13.1 % (<15 %)	
Leaching-adsorption-desorption (835.1230)	Parent Kf of 46-79 (L/kg) Koc of 3,883-8,778 (L/kg)	Fenpropimorph acid Kf of 0.5-1 (L/kg) Koc of 42-111 (L/kg)	45857318 Parent fenpropimorph is slight mobile and fenpropimorph acid is mobile to highly mobile in soil and sediment based on Koc values and FAO

Guideline	Parameter ($T_{1/2}$ unless stated)	Significant degradation products	Reference (MRID)/ Comments
			soil mobility classification[2]
Leaching from treated wood (AWPA E20-08)	Leaching rates (ug/cm^2/day) 0.85 (max) 0.18 (average) 0.00047 (min) Cumulative leaching (ug/cm^2) 17.9 (average)	N/A	46074205

4.1.2 Leaching from Wood

Pine wood was treated and leached using rainfall. The maximum and average leaching rates were 0.85 and 0.18 µg/cm^2/day and the cumulative leaching was 17.9 µg/cm^2 over a 237-day period (MRID 46074205).

4.1.3 Water, Sediment, and Soil

Fenpropimorph is stable to hydrolysis (MRID 45857216) and to photodegradation in water (MRID 46074201). For aerobic aquatic metabolism, the half-lives of parent fenpropimorph in two loamy sand systems containing water and sediment were 59 and 38 days, respectively. The aerobic aquatic half-lives for the degradate fenpropimorph acid in one of the sediment water systems was 94 days, but no degradation was observed in the other system. Residues of parent fenpropimorph were generally higher in sediment than water but water residues were higher for fenpropimorph acid (MRID 45868904). In two soils, parent fenpropimorph was slightly mobile with Freundlich Kads values of 46 and 79 L/kg and Koc values of 3,833 and 8,778 L/kg in loamy sand and sandy loam soils. On the other hand, the degradate fenpropimorph acid was mobile to highly mobile with Freundlich Kads values of 0.5 and 1 L/kg and Koc values of 42 and 111 L/kg in loamy sand and sandy loam soils (MRID 45857318)[3].

The log P value of parent fenpropimorph is 4.1 which would typically trigger the need for requiring bioconcentration in fish (850.1735) data (>3). However, the Agency expects environmental residues of parent fenpropimorph and fenpropimorph acid to be low as discussed above (section 4.1.1). Therefore, these data are not needed for risk assessment.

4.1.4 Data Gaps

There are no environmental fate data gaps for fenpropimorph or fenpropimorph acid.

[2] FAO, http://www.fao.org/docrep/003/x2570e/x2570e06.htm
[3] Log Koc values of 0-2 are mobile to highly mobile and Log Koc values of 3-4 are considered to be slightly mobile (http://www.fao.org/docrep/003/x2570e/x2570e06.htm)

4.1.5 Degradates of Potential Concern

The only known degradation product of potential environmental concern is fenpropimorph acid, which is a once-demethylated form with a carboxylic acid group. This degradation product forms in metabolism studies in aerobic soil (MRID 45857217) and in sediment systems (MRID 45868904). In water sediment systems, it is formed in significant amounts (≥10 %) from sorbed parent fenpropimorph and repartitions to the water phase. Fenpropimorph acid was mobile to highly mobile in two soils (MRID 45857218) which has the potential to result in transport of fenpropimorph acid to aquatic systems where it will partition to the water phase. However, the Agency expects environmental residues of both parent fenpropimorph and fenpropimorph acid to be low based on the reasons discussed above (section 4.1.1).

4.1.6 Water Quality – Total Daily Maximum Load

Fenpropimorph and fenpropimorph acid are not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act.[4] In addition, no Total Maximum Daily Loads (TMDL) have been developed for fenpropimorph.[5] More information on impaired water bodies and TMDLs can be found at EPA's website.[6]

4.2 Aquatic Exposure

4.2.1 Exposure Modeling

The Agency did not conduct a Down-the Drain (DtD) assessment to estimate environmental exposure because the end-use label states that wastes produced at the site of application must be treated as hazardous waste and disposal must be conducted based on the label instructions, a state pesticide or environmental control Agency, or by guidance from hazardous waste representative.

4.2.2 Monitoring Data

The Agency is not aware of any surface or ground water monitoring data for parent fenpropimorph or fenpropimorph acid. A search of the USGS Water Quality Portal[7] as of December 5th, 2019 does not include monitoring data for parent fenpropimorph or the degradation product fenpropimorph acid.

4.2.3 Selected Ecotoxicity Endpoints

Ecotoxicity endpoint data are used as measures of effects to aquatic and terrestrial organisms. All available ecotoxicity endpoints are tabulated in Table 7. The most sensitive values for each receptor group are used for the risk assessment. Some of the available data had endpoints lower than those listed below, however, these studies tested the end use product (EUP) which contained

[4] http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885
[5] http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES
[6] http://www.epa.gov/owow/tmdl/
[7] https://www.waterqualitydata.us/

other chemicals, *i.e.*, propiconazole and boric acid (see Appendix B). The lower endpoints are likely due to the other chemicals in the formulation tested and not to fenpropimorph. Therefore, these endpoints were not used in the assessment.

Table 7– Ecological Effects Endpoints for Parent Fenpropimorph[1]

Receptor Group	Surrogate Species	Risk Scenario	Toxicity Endpoint	Reference (MRID)
Freshwater fish	Bluegill Sunfish	Acute	96-h LC_{50} = 3.25 mg/L	45857205
	Rainbow Trout	Chronic	NOAEC < 0.016 mg/L	46074303
Freshwater invertebrates	Daphnia magna	Acute	48-h EC_{50} = 12.24 mg/L	45847207
		Chronic	NOAEC = 0.082 mg/L	46074305
Freshwater benthic invertebrates	Freshwater midge	Subchronic/ Chronic	10-day LC_{50} = 13 mg/kg NOAEC = 4.9 mg/kg	47425201
Estuarine/marine fish	Sheepshead minnow	Acute	Waived	--
		Chronic	Not required[2]	--
Estuarine/marine invertebrates	Mollusk	Acute	Waived[3]	--
	Shrimp	Acute	Waived	--
		Chronic	Not required[2]	--
Estuarine/marine benthic invertebrates	Marine amphipod	Subchronic/ Chronic	Waived	--
Algae	Green alga	N/A[4]	96-hr EC_{50} = 0.327 mg/L NOAEC = 0.0003 mg/L	45868903
Aquatic vascular plants	Duckweed	N/A	Waived	--
Birds	Northern bobwhite quail	Acute	LD_{50} ≥2000 mg/kg	45868901
	Mallard duck	Subacute dietary	LC_{50} = 5000 mg/kg	45857204
		Chronic	Not required[2]	--
Non-target insects	Honey bee	Acute	Oral LC_{50} ≥95.6 ug ai/bee Contact LC_{50} ≥100 ug ai/bee	47125501

[1] Terrestrial plant data are available for the formulated product (see Appendix B)
[2] Not required for this use pattern
[3] Waived for this chemical based on its use as an antisapstain wood preservative. This limited use pattern would lead to minimal exposure to non-target organisms.
[4] N/A = not applicable

For the degradate fenpropimorph acid, the registrant submitted three acute toxicity studies on freshwater aquatic organisms and the results are summarized in Table 8.

Table 8-Aquatic Toxicity Values for Parent Fenpropimorph and Fenpropimorph Acid

Species	Fenpropimorph (mg ai/L)	Fenpropimorph acid (mg ai/L)	Reference (MRID)
Rainbow trout	LC_{50} = 5.15	$LC_{50} \geq 100$	47425202
Green algae	EC_{50} = 0.327	$EC_{50} \geq 100$	47422503
Daphnia magna	EC_{50} = 12.24	$EC_{50} \geq 100$	47422504

The higher acute LC_{50} and EC_{50} values for fenpropimorph acid relative to parent fenpropimorph in Table 8 indicate that fenpropimorph acid is less toxic to aquatic plants and animals than fenpropimorph. It could be assumed that fenpropimorph acid is less toxic on a chronic basis as well, however, no comparative studies are available to confirm this assumption.

Available data indicate that the multiple active ingredient EUP is more toxic to aquatic organisms than parent alone (Appendix B). This is likely due to the additional active ingredients (*i.e.,* boric acid and propiconazole) present in the product.

4.3 Ecological Risk Characterization

4.4 Incident Data

There were no reported ecological incidents for Fenpropimorph in the Agency's Incident Data System (IDS) as of 10/21/19.

4.5 Summary of Major Risk Presumptions

The Agency has determined that adverse effects to terrestrial animals, aquatic freshwater animals, and aquatic plants are expected to be minimal for the antisapstain use of fenpropimorph. The labeling restrictions listed above are expected to protect non-target species from antisapstain treated and stored wood. This restricted use pattern would cause minimal exposure to both terrestrial (including bees) and aquatic non-target organisms. The primary degradate, fenpropimorph acid, is not a risk concern to non-target terrestrial and aquatic organisms based on a lack of toxicity and a lack of exposure (MRIDs 47425202, 47425203, and 47425204).

Typically, wood treatment uses can result in Down-the-Drain releases from treatment and storage of wood. However, for fenpropimorph, the Agency did not conduct a Down-the-Drain assessment for treatment and storage of wood at industrial use sites because the sole end-use label (EPA Reg. No. 71406-4) states that wastes must be treated as hazardous waste and disposal must be conducted according to label instructions, a state pesticide or environmental control Agency, or by guidance from a hazardous waste representative. Consequently, down-the-drain releases from industrial use of fenpropimorph are not expected.

4.6 Major Uncertainties and Data Gaps

There are no major uncertainties for the antisapstain use of fenpropimorph. All data requirements have been met with either submitted data or approved waivers. Therefore, no additional data are needed for this risk assessment.

5 LISTED SPECIES OF CONCERN

There is no reasonable expectation for the use of fenpropimorph to cause direct or indirect adverse effects to threatened and endangered species based on low exposure potential in terrestrial and aquatic environments. This is based on the label restrictions of storage of treated lumber and additionally, this product is intended to protect wood prior to sale and is not intended to protect lumber at the use site. Fenpropimorph also has low leach rates as well as limited soil mobility and is not expected to reach aquatic environments.

EPA is making a "no effect" determination under the Endangered Species Act (ESA) for all listed species and designated critical habitat, and has, therefore, concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under ESA section 7(a)(2) is not required for the antisapstain use of fenpropimorph on wood products.

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APPENDIX A: Toxicology Profile

The acute toxicity profile for end-use-product fenpropimorph is presented in Table A1. Fenpropimorph has low acute toxicity via the oral, dermal, and inhalation routes of exposure (Toxicity Category III and IV). Fenpropimorph has been classified as Toxicity Category II for acute eye irritation and Toxicity Category I for dermal irritation as the chemical showed severe irritation after one hour exposure in rabbits. The skin sensitization potential for this fenpropimorph end-use-product has not been tested.

Table A1. Fenpropimorph End-Use-Product (5.4% a.i.) Acute Toxicity Profile

Guideline Number	Study Type	MRID Number	Results	Toxicity Category
870.1100	Acute Oral – Rat	45857203	LD_{50} >2000 mg/kg (males, females, combined)	III
870.1200	Acute Dermal – Rat	45857204	LD_{50} > 2000 mg/kg (males, females, combined)	III
870.1300	Acute Inhalation – Rat	45857205	LC_{50} = 3.62 mg/L (males), 1.59 mg/L (females) (combined not reported)	IV
870.2400	Acute Eye Irritation – Rabbit	45857206	Severely irritating	I
870.2500	Acute Dermal Irritation – Rabbit	45857207	Severely irritating and irreversible damage	I
870.2600	Dermal Sensitization – guinea pig	[a]	[a]	N/A

Table A2 shows the fenpropimorph acute, subchronic and chronic toxicity studies for this registration review and the points of departure and endpoints established from each study.

Table A2. Acute, Subchronic and Chronic Toxicity Values for Fenpropimorph

Acute		
Guideline number/Study Type/Test Substance (% a.i.)	MRID number (Year)/Citation/Classification/Doses	Results
870.1100 Acute Oral Toxicity Study Hen 92.5% a.i. Gavage	44323909 (1980) Acceptable/Guideline 250, 500, 1000, 2000, 4000 mg/kg	Oral LD_{50} Protected = 1700 mg/kg Unprotected = 1600 mg/kg
870.6100 Acute Delayed Neurotoxicity of	44323909 (1980) Acceptable/Guideline 425, 850, 1700 mg/kg	NOAEL ≥1700 mg/kg LOAEL

Organophosphorus Substances Hen 92.5% a.i. Gavage		Not established
870.6200 Acute neurotoxicity screening battery Rat 94.3% a.i. Gavage	44323910 (1997) Acceptable/Guideline M/F = 0, 100, 500, 1500 mg/kg (single gavage dose)	NOAEL M: 500 mg/kg F: 500 mg/kg LOAEL M: 1500 mg/kg based on piloerection observations during the clinical examinations and FOB. F: 1500 mg/kg based on piloerection observations during the clinical examinations and FOB and decreased overall motor activity.
Subchronic		
Guideline number/Study Type/Test Substance (% a.i.)	MRID number (Year)/Citation/Classification/Doses	Results
870.3100 90-day oral toxicity Rat 91.1% a.i. Dietary	44380103 (1979) Acceptable/Guideline ppm = 0, 6.25, 12.5, 25 M = 0, 0.382, 0.768, 1.54 mg/kg/day F = 0, 0.465, 0.915, 1.80 mg/kg/day	NOAEL M: 1.54 mg/kg/day F: 1.80 mg/kg/day LOAEL Not established
870.3100 870.6200 90-day oral toxicity and neurotoxicity Rat 94.3% a.i. Dietary	44380105 (1997) Acceptable/Guideline ppm = 0, 1, 100, 1000 M = 0, 0.1, 0.7, 7.1, 71.0 mg/kg/d F = 0, 0.1, 0.8, 8.5, 77.7 mg/kg/d [FOB and motor activity days – 7, 22, 50, 85; 5/sex/group profused neurohistology exams]	**SYSTEMIC** NOAEL M = 7.1 mg/kg/day F = 8.5 mg/kg/day LOAEL M: 71.0 mg/kg/day based on decreased BW and BWG. F: 77.7 mg/kg/day based on decreased BW and BWG. **NEUROTOXICITY** NOAEL M = 71.0 mg/kg/d F 8.5 mg/kg/d LOAEL

		M: Not established F: 77.0 mg/kg/d based on differences in landing foot splay values
870.3200 28-Day dermal toxicity Rat 96.6% a.i.	45868902 (2001) Acceptable/Guideline M = 0, 0.2, 0.6, 2.0 mg/kg/d F = 0, 0.2, 0.6, 2.0 mg/kg/d	Dermal and Systemic: NOAEL M: 2.0 mg/kg/d F: 2.0 mg/kg/d LOAEL M: Not established F: Not established **NOTE**: from a range finding study, the material was tested at the maximum dose that would not produce severe skin irritation. Multifocal scale formation at ≥ 0.1% (w/w) was observed in both sexes. **NOTE:** Based on the average weight calculated at day 28 in the study (318.5 g), the highest dose tested (2.0 mg/kg/day) and a *k* factor of 9.83, the dermal loading equivalent is 1.36 µg/cm^2.
870.3150 90-day oral toxicity Dog 91.1% a.i. Dietary	44380104 (1979) Acceptable/Guideline ppm = 0, 50, 100, 200, 400 M = 0, 1.46, 2.96, 6.40, 11.63 mg/kg/day F = 0, 1.77, 3.69, 7.92, 14.64 mg/kg/day	NOAEL M = 11.63 mg/kg/day F = 14.64 mg/kg/day LOAEL M: Not established F: Not established
Chronic		
Guideline number/Study Type/Test Substance (% a.i.)	MRID number (Year)/Citation/Classification/Doses	Results
870.4300 Combined Chronic oral toxicity and carcinogenicity Rat 92.5% a.i. Dietary	44380106 (1982) Acceptable/Guideline ppm = 0, 5, 10, 50, 250 M = 0, 0.2, 0.3, 1.7, 8.8 mg/kg/day F = 0, 0.2, 0.4, 2.1, 11.2 mg/kg/day	NOAEL: M = 8.8 mg/kg/d F = 11.2 mg/kg/d LOAEL: Not established
870.4100 53-week chronic toxicity	44323911 (1990) Acceptable/Guideline	NOAEL: M = 12.3 mg/kg/day

Dog ≥94.7% a.i. Dietary	 ppm = 0, 25, 100, 400 M = 0, 0.8, 3.2, 12.3 mg/kg/day F = 0, 0.8, 3.2, 13.2 mg/kg/day	F = 13.2 mg/kg/day LOAEL: Not established
870.4200 Carcinogenicity study Mouse 92.5% a.i. Dietary	44380107 (1982) Acceptable/Guideline ppm = 0, 5, 30, 150, 1000 M = 0, 0.5, 3.0, 16, 106 mg/kg/d F = 0, 0.5, 3.5, 17, 118 mg/kg/d	NEW: NOAEL M = 106 mg/kg/day F = 118 mg/kg/day LOAEL M: Not established F: Not established
Developmental Toxicity and Reproduction		
Guideline number/Study Type/Test Substance (% a.i.)	MRID number (Year)/Citation/Classification/Doses	Results
870.3800 Reproduction and fertility effects Rat 92.5% a.i. Dietary	44323915 (1982) Acceptable/Non-guideline ppm = 0, 6.25, 12.5, 25 M = 0, 0.51, 1.03, 2.04 mg/kg/d F = 0, 0.71, 1.46, 2.79 mg/kg/d	**PARENTAL** NOAEL: M = 2.04 mg/kg/d F = 2.79 mg/kg/d LOAEL: M: Not established F: Not established **REPRODUCTION** NOAEL: M = 2.04 mg/kg/d F = 2.79 mg/kg/d LOAEL: M: Not established F: Not established **OFFSPRING** NOAEL: M = 2.04 mg/kg/d F = 2.79 mg/kg/d LOAEL: M: Not established F: Not established
870.3700 Prenatal developmental toxicity Rat 92.5% a.i. Gavage	44380108 (1978) Acceptable/Guideline (PRE-GLP) 2000 – Supplemental submission of data concerning test article preparation, solubility and stability (no MRID #)	**MATERNAL** NOAEL = 40 mg/kg/day LOAEL = 160 mg/kg/day based on clinical signs of toxicity (vaginal bleeding) and decreased body weight and body weight gain; decreased live fetuses/dam,

	F: 0, 2.5, 10, 40, 160 mg/kg/day	increase resorptions, and increased postimplantation loss. **DEVELOPMENTAL** NOAEL = 40 mg/kg/d LOAEL = 160 mg/kg/d based on decrease live fetuses/dam, increased resorptions, increased postimplantation loss, increased incidence of cleft palate.
870.3700 Prenatal developmental toxicity Rat 92.5% a.i. Gavage	44323912 (1979) Acceptable/Guideline (Dosing during gestation and lactation; partial developmental neurotox through PND 21) 2000 – Supplemental submission of data concerning test article preparation, solubility and stability (no MRID #) mg/kg/day = 0, 2.5, 10, 40, 160	**MATERNAL** NOAEL = 10 mg/kg/d LOAEL = 40 mg/kg/d based on decrease # live fetuses/dam, increase % postimplantation loss, decreased mean litter size and # live pups, decrease survival indices. **DEVELOPMENTAL** NOAEL = 10 mg/kg/d LOAEL = 40 mg/kg/d based on decrease # live fetuses/dam, increase % postimplantation loss, decreased mean litter size and # live pups, decrease survival indices. **NEUROTOXICITY** NOAEL = 10 mg/kg/d LOAEL = 40 mg/kg/d based on decreased F grip strength.
870.3700 Prenatal developmental toxicity Rabbit 95.6% a.i. Gavage	44323914 (1993) Acceptable/Guideline F: 0, 7.5, 15, 30 mg/kg/day (GD 7-19)	**MATERNAL** NOAEL = 15 mg/kg/d LOAEL = 30 mg/kg/d based on clinical signs (9/20 animals swelling of anus GD 15-29). **DEVELOPMENTAL** NOAEL = 15 mg/kg/d LOAEL = 30 mg/kg/d based on cleft palate 4/116 fetuses (2/20 litters); anomalies (increased incidence of external, visceral, and skeletal malformations, increased incidence of external and skeletal anomalies, and increased incidence of skeletal variations).
870.3700	44323913 (1980) Acceptable/Guideline	**MATERNAL** NOAEL = 12 mg/kg/d

Prenatal developmental toxicity Rabbit 92.5% a.i. Gavage	F: 0, 0*, 2.4, 12, 36*, 60 mg/kg/day (mortality at 60 mg/kg/day) *Supplementary groups were added because of mortality at 60 mg/kg/day: 0 or 36 mg/kg/d	LOAEL = 36 mg/kg/d based on mortality, abortions and clinical signs of toxicity. **DEVELOPMENTAL** NOAEL = 12 mg/kg/d LOAEL = 36 mg/kg/d based on increased incidence of resorptions, external anomalies and skeletal variations/retardations.
Mutagenesis		
Guideline number/Study Type/Test Substance (% a.i.)	MRID number (Year)/Citation/Classification/Doses	Results
870.5100 Reverse Gene Mutation Assay *Salmonella typhimurium* 95.6% a.i.	44323917 (1994) Acceptable/Guideline Trial 1: TA98, TA100, TA1535, TA1537 0, 20, 100, 500, 2500, 5000 µg/plate (±S9) Trial 2: TA98 0, 5, 10, 20, 40, 80 µg/plate (±S9) Trial 3: TA100, TA1535, TA1537 0, 6, 12, 25, 50, 100 µg/plate (±S9) TA98 0, 20, 100, 500, 2500, 5000 µg/plate (±S9) Trial 4 (Pre-incubation test) TA100, TA1535, TA1537 0, 6, 12, 25, 50, 100 µg/plate (±S9) TA98 0, 4, 20, 100, 500, 1000 µg/plate (±S9)	No evidence of induced mutant colonies over background.

870.5375 *In vitro* Chinese hamster lung cells 95.6% a.i.	44323919 (1995) Acceptable/Guideline S9 Activation Experiment 1: 0, 0.5, 1.0, 2.0 µg/mL Experiment 2: 0, 1.0, 2.0, 3.0 µg/mL S9 Non-activation Experiment 1: 0, 10, 20, 30 µg/mL Experiment 2: 0, 10, 20, 30 µg/mL	There were no treatment-related increases in total aberration frequency at any dose level with or without metabolic activation.
870.5395 *In vivo* Mammalian Cytogenetics – micronucleus assay Mice 95.6% a.i.	44323918 (1994) Acceptable/Guideline Experiment 1: 0, 250, 500, 1000 mg/kg Experiment 2: 0, 1000 mg/kg	No significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow at any dose at any sampling time.
870.5550 Unscheduled DNA synthesis in primary hepatocytes Rat 94.7% a.i.	44323916 (1988) Acceptable/Guideline 0, 0.100, 0.250, 0.500, 1.00, 2.50, 5.00, 10.0 µg/mL	There was no evidence that unscheduled DNA synthesis, as determined by radioactive tracer procedures, was induced.
Special		
Guideline number/Study Type/Test Substance (% a.i.)	MRID number (Year)/Citation/Classification/Doses	Results
Cholinesterase inhibition Rat 99.1% a.i. Intraperitoneal	44380109 (1980) Unacceptable 0, 200, 650, 2000 mg/kg	
870.7485 Metabolism and pharmacokinetics Rat >98.4% a.i.	44323920 (1989) Unacceptable/Non-guideline 1.25 mg/kg/day single gavage 1.25 mg/kg/day single intravenous 1.25 mg/kg/day single gavage after 14 days of 1.25 non-radioactive; or as repeated dose for 7 consecutive days. 100 mg/kg/day single gavage	
Hepatic drug-metabolizing activity	44323921 (1981) Acceptable/Non-guideline	Administered for 14 days to males; phenobarbitone was

Rat Dietary .	0, 25, 50, 1600 ppm	positive control; microsomal and cytosolic xenobiotic metabolizing enzyme activities were measured and hepatocyte ultrastructure investigated. No differences from control in urinary excretion of ascorbic acid which differed from pentobarbitone sleeping times. No differences in crotol in P-450 or in plasma cholinesterase. Increase in aniline hydroxylase, ethylmorphine-N-demethylase, glucoronyltransferase and glutathione S-transferase. Relative liver weights increased at 250 and 1600 ppm; no changes in hepatic morphology.

APPENDIX B: Ecotoxicity Profile

Toxicity to Terrestrial Receptors

Birds:

Two acute avian toxicity studies are available using technical fenpropimorph (see Table B1). Fenpropimorph is practically non-toxic when administered orally or as a sub-acute dietary treatment to avian test species. Both studies are acceptable and fulfill the guideline requirement for avian acute toxicity (MRIDs 45868901, 45857204).

Plants:

A Tier I vegetative vigor non-target plant toxicity test was conducted on 10 vascular plants to determine if the maximum recommended label dosage is phytotoxic to plants (maximum dose = 2.25 L FP/Ha-based on nominal content of a.i.). If greater than 25% injury or growth reduction occurs, the pesticide is considered phytotoxic and Tier II studies are triggered. In this Tier I study (MRID 46074306), fenpropimorph was phytotoxic based on growth at greater than 25% to plants. The most sensitive monocot was corn, and the most sensitive dicot was cabbage). Fenpropimorph Tier II dose response studies for seedling emergence and vegetative vigor are not required for the rooted aquatic macrophyte rice (*Oryza sativa*). No terrestrial plant species are required to be tested by the Antimicrobial Division (AD) at the Tier II level based on a lack of exposure terrestrial plants from AD uses. The Tier I vegetative vigor study is acceptable and fulfills the guideline requirement for 850.4150 (MRID 46074306).

Toxicity to Aquatic Receptors

Acute Aquatic Ecotoxicity Studies:

Freshwater Fish:

Three acute freshwater fish toxicity studies are available. Two studies, one using the Rainbow trout and one using the Bluegill sunfish, are technical grade tests. In both studies, the fenpropimorph was moderately toxic to freshwater fish. In the third test, the end-use formulation was used. In this study, the fenpropimorph, propiconazole, boric acid mixture was highly toxic to freshwater fish on an acute toxicity basis ($LC_{50} \geq 0.74$ mg/L, NOAEC = 0.10 mg/L). These studies are acceptable and fulfill the guideline requirement for freshwater fish acute toxicity tests (MRIDs 45857205, 45857206, 46070203).

Estuarine/Marine Fish:

No studies are available for the technical. However, the registrant has off-labeled the use of fenpropimorph in estuarine/marine habitats and therefore these data are not required.

Freshwater Invertebrates:

Two acute freshwater invertebrate toxicity tests are available using the *Daphnia magna*. In the first, technical grade fenpropimorph was used. Fenpropimorph technical grade was slightly toxic. In the second study, the end-use formulation was used. The fenpropimorph, propiconazole, boric acid mixture was highly toxic to freshwater aquatic invertebrates on an acute toxicity basis (LC_{50} = 0.30 mg/L, NOAEC = 0.10 mg/L, MRIDs 45857207, 46074204).

Estuarine/Marine Invertebrates:

No studies are available for fenpropimorph technical. However, the registrant has off-labeled the use of fenpropimorph in estuarine/marine habitats and therefore these data are not required.

Chronic Aquatic Ecotoxicity Studies:

Freshwater Chronic Fish and Invertebrates:

Two chronic aquatic animal studies are available for technical grade fenpropimorph, a fish early life test using the Rainbow trout, and an invertebrate life cycle study using *Daphnia magna*. The most sensitive species is the freshwater fish having a NOAEC <0.00016 mg/L (body length). Both studies are acceptable and fulfill the guideline requirements for chronic freshwater fish and invertebrates (MRIDs 46074303, 46074305).

Estuarine/Marine Fish and Invertebrates:

No studies are available for fenpropimorph technical or end-use product. However, the registrant has off-labeled the use of fenpropimorph in estuarine/marine habitats and therefore these data are not required.

Based on environmental fate data, fenpropimorph is either tightly bound to soil or converted to fenpropimorph acid. In laboratory studies, fenpropimorph acid (BF 421-2) was detected in sediment with concentrations ranging from 6.2% to 9.1%. Fenpropimorph acid is not tightly bound to soil and has potential to move from the treatment (or storage) site. Aquatic invertebrate acute toxicity tests are 48 hours in duration, fish studies are 96 hours in duration, and algal toxicity studies are 96 to 120 days in duration. It is assumed that conversion from fenpropimorph parent to fenpropimorph acid will occur to some extent in aquatic toxicity tests. Table B1 contains the results of submitted ecological toxicity studies for fenpropimorph

Table B1. Summary of ANTISAPSTAIN Fenpropimorph Ecotoxicity Studies

Study/Species	MRID Number	Study Results	Status of Study

Birds			
Avian Acute Oral – 96.6% **850.2100**/71-1 Bobwhite quail	45868901	LD_{50} ≥2000 mg/Kg NOAEC = 1000 mg/kg	CORE - Practically non-toxic.
Avian Sub-Acute Dietary – 94.7% **850.2200**/71-2 Mallard duck	45857204	LC_{50} = 5000 mg/Kg NOAEL = 1250 mg/Kg	CORE - Practically non-toxic.
Terrestrial Invertebrates			
Acute Nontarget Insect - Honey bee TGAI 95.7% **850.3020 acute oral** **860.3030 acute contact**	47125501	ORAL LC_{50} ≥95.6 ug ai/bee NOAEC = 6.25 ug ai/bee CONTACT LC_{50}≥100 ug ai/bee NOAEC = 6.25 ug ai/bee	Supplemental – Not repairable, must be repeated.
Aquatic Animals			
Acute Freshwater Invert. - 96.6% **850.1010**/72-2 *Daphnia magna*	45857207	EC_{50} = 12.24 mg/L NOAEC = 1.0 mg/L	CORE – Slightly toxic.
Acute Freshwater Invert.- Form. * **850.1010**/72-2 *Daphnia magna*	46074204	LC_{50} = 0.30 mg/L NOAEC = 0.10 mg/L	CORE – Highly toxic
Acute Freshwater Invert.- Fenpropimorph. Acid – 99.8% 850.1010/72-2 *Daphnia magna*	47425204	EC_{50} ≥ 100 mg/L NOAEC ≥ 100 mg/L	Supplemental – Not repairable.
Acute Estuarine/Marine Invert. TGAI **850.1035** Mysid shrimp	NA	NA	Waived
Acute Estuarine/Marine Invert. TGAI **850.1055** E. Oyster embryo larvae	NA	NA	Waived
Acute Freshwater Fish- 96.6% **850.1075**/72-1c Rainbow trout Oneorhyn*chus mykiss*	45857206	LC_{50} = 5.15 mg/L NOAEC = >1.0 mg/L	CORE – Moderately toxic
Acute Freshwater Fish- Form.* **850.1075**/72-1c Rainbow trout Oneorhyn*chus mykiss*	46074203	LC_{50} ≥ 0.74 mg/L NOAEC = 0.10 mg/L	CORE – Highly toxic
Acute Freshwater Fish- Fenpropimorph	474252-02	LC_{50} ≥ 100 mg/L NOAEC ≥ 100 mg/L	Supplemental – Not repairable.

Acid 99.8% **850.1075**/72-1c Rainbow trout Oneorhyn*chus mykiss*			
Acute Freshwater Fish - 96.6% **850.1075**/72-1a Bluegill sunfish Lepo*mis macrochirus*	45857205	LC_{50} = 3.25 mg/L NOAEC = 0.63 mg/L	CORE – Moderately toxic
Acute Estuarine/Marine Fish TGAI **850.1075**	NA	NA	Waived
Acute Sediment Freshwtr Inverts. Fen.Acid **850.1735**	NA	NA	Waived
Acute Sediment Marine Inverts. Fen.Acid **850.1740**	NA	NA	Waived
Acute Sediment Freshwtr Inverts. Fenpropimorph Acid – 95.6% *Chironomous riparius* **850.1790**	47425201	$EC_{50} \geq 0.000125$ mg/L NOAEC ≥ 0.000125 mg/L	Supplemental – Not repairable.
Plants			
Rooted Aquatic - Rice **850.4225**/123-1 *Oryza sativa*	NA	NA	Waived
Veg. Vigor – Cabbage Form.* Most sensitive dicot **850.4150**/122-1 *Brassica oleracea*	46074306	EC_{25} > 25% effect Tier II data triggered.	Supplemental Tier II data Waived
Veg. Vigor – Corn Form* Most sensitive monocot **850.4150**/122-1 *Zea mays*	46074306	EC_{25}> 25% effect Tier II data triggered.	Supplemental Tier II Waived
Floating macrophyte **850.4400**/123-2 Duckweed *Lemna gibba*	NA	NA	Waived
Blue-green cyanobacteria **850.5400**/123-2 *Anabaena flos-aquae*	NA	NA	Waived
Green algae - 96.6% **850.5400**/123-2 *Selenastrum capricornutum*	45868903	EC_{50} = 0.327 mg/L NOAEC = 0.0003 mg/L	Supplemental

Green algae - Fenpropimorph Acid - 99.8% **850.5400**/123-2 *Selenastrum capricornutum*	47425203	$EC_{50} \geq 100$ mg/L NOAEC= >25 mg/L	Supplemental. Not repairable.
Freshwater diatom **850.5400**/123-2 *Navicula pelliculosa*	NA	NA	Waived
Marine diatom **850.5400**/123-2 *Skeletonema costatum*	NA	NA	Waived
Chronic Aquatic Tests			
Fish Early Life -95.6% **850.1400**/72-4a Rainbow trout *Oncorhynchus mykiss*	46074303	NOAEC ≤ 0.016 mg/L for body length NOAEC = 0.016 mg/L for body weight	CORE
Aquatic Invertebrate Life Cycle - 95.4% **850.1300**/72-4b *Daphnia magna*	46074305	NOAEC = 0.082 mg/L EC50 = 0.41 mg/L	CORE

***Formulation – End-use product (fenpropimorph=5.4%, propiconazole=2.7%, boric acid = 9.0%).**

**** Studies submitted in support of ecotoxicity data waiver requests.**

References:

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MRID 45857206: Fenpropimorph*:* Acute toxicity study on the rainbow trout (*Oncorhynchus mykiss* Walbaum 1792) in a static system (96 hours). December 2, 1999. Department of Toxicology BASF Aktiengesellschaft D-67056 Ludwigshafen/Rhein, Germany. ID: 121F0235/995026

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MRID 45868901: Fenpropimorph - Avian Single Dose Oral LD_{50} on the Bobwhite Quail (*Colinus virginianus*). February 3, 2000. Experimental Toxicology and Ecology BASF Aktiengesellschaft 67056 Ludwigshafen/Rhein, Germany. Report ID: 11W0235/99037

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